

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

<b>Date of mailing (day/month/year)</b> 21 December 1998 (21.12.98)	in its capacity as elected Office
<b>International application No.</b> PCT/AU98/00368	<b>Applicant's or agent's file reference</b> 80456
<b>International filing date (day/month/year)</b> 19 May 1998 (19.05.98)	<b>Priority date (day/month/year)</b> 19 May 1997 (19.05.97)
<b>Applicant</b>	
VESEY, Graham et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

03 December 1998 (03.12.98)

in a notice effecting later election filed with the International Bureau on:

2. The election  was  was

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p><b>The International Bureau of WIPO</b> <b>34, chemin des Colombettes</b> <b>1211 Geneva 20, Switzerland</b></p>	<p><b>Authorized officer</b></p> <p><b>E. Huchon</b></p>
<p><b>Facsimile No.: (41-22) 740.14.35</b></p>	<p><b>Telephone No.: (41-22) 338.83.38</b></p>

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/18504

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :Please See Extra Sheet.

US CL :536/22.1, 23.7; 435/7.2, 7.32, 7.35, 29, 30, 32, 38, 252.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 536/22.1, 23.7; 435/7.2, 7.32, 7.35, 29, 30, 32, 38, 252.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Dialog  
search terms, *Salmonell?*, secreted proteins, *Ssp?*, *prg?*

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HUECK et al. <i>Salmonella typhimurium</i> secreted invasion determinants are homologous to <i>Shigella</i> Ipa proteins. <i>Molecular Microbiology</i> . 1995, Vol. 18, No. 3, pages 479-490, see entire document.	1, 2, 4, 10, 16
X	HANTMAN et al. Defective Extracellular Protein Secretion by <i>Salmonella typhimurium</i> Mutants Impaired in Induction of Eucaryotic Cell Membrane Ruffling and Macrophagocytosis. Abstracts of the 95th General Meeting of the American Society of Microbiology. 21-25 May 1995, page 184, Abstract B-109, see entire abstract.	17-19

<input checked="" type="checkbox"/>	Further documents are listed in the continuation of Box C.	<input type="checkbox"/>	See patent family annex.
*A*	Special categories of cited documents:	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*B*	document defining the general state of the art which is not considered to be of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*L*	earlier documents published on or after the international filing date which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*O*	document referring to an oral disclosure, use, exhibition or other means	*A*	document member of the same patent family
*P*	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
12 FEBRUARY 1997	21 MAR 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer H. F. SIDBERRY Telephone No. (703) 308-0196

Form PCT/ISA/210 (second sheet)(July 1992)\*

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/18504

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	BAUDRY et al. Nucleotide sequence of the invasion plasmid antigen B and C genes ( <i>IpAB</i> and <i>IpAC</i> ) of <i>Shigella flexneri</i> . Microbial Pathogenesis. 1988, Vol. 4, pages 345-357, see pages 348 and 349	1, 2, 4, 10, 16
X	WO 95/02048 A (THE GENERAL HOSPITAL CORPORATION) 19 January 1995, see especially pages 11, 12, 19, 70 and 90-102.	1, 2, 4, 10, 16-19

Form PCT/ISA/210 (continuation of second sheet)(July 1992)\*

**INTERNATIONAL SEARCH REPORT**

International application No.  
PCT/US96/18504

**A. CLASSIFICATION OF SUBJECT MATTER:**  
IPC (6):

C07H 19/00, 21/00, 21/04; C12N 1/21; C12Q 1/02, 1/10, 1/18, 1/24; G01N 33/569

**BOX I. OBSERVATIONS WHERE CLAIMS WERE FOUND UNSEARCHABLE**  
2. Where no meaningful search could be carried out, specifically:

A sequence listing is required for all disclosures of sequence information in which the sequence has four or more amino acids or ten or more nucleotides. The PCT application does not comply with Section 1.821(e), (a printable copy of the "Sequence Listing") a computer readable form, as defined in Sections 1.82(c), 1.822 and 1.823, recorded as a single file on either a diskette or a magnetic tape. The claims recite Sequence Identifiers, but do not comply with the stated requirements, and therefore, no meaningful search could be carried out on claims 3,5, and 11.

**BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING**  
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I, claims 1, 2, 4, 6-10, and 12-19, drawn to DNA encoding a *Salmonella* secreted protein (Ssp), cell, method of inducing the uptake of a bacterial cell.

Group II, claims 20 and 22, drawn to SspC polypeptide.

Group III, claims 23 and 25, drawn to SspD polypeptide.

Group IV, claims 26 and 28, drawn to SspH polypeptide.

Group V, claims 29 and 31, drawn to IgB polypeptide.

Group VI, claim 32, drawn to antibody which binds a Ssp.

Group VII, claim 33, drawn to methods of detecting a *Salmonella* infection using DNA.

Group VIII, claim 34, drawn to method of detecting a *Salmonella* infection using antibody.

Group IX, claims 35 and 36 drawn to method of targeting an antigen to an epithelial cell.

Group X, claim 37, drawn to method of inducing a cytotoxic T cell response.

Group XI, claims 38-41, drawn to vaccines comprising attenuated bacteria and a method of vaccinating.

Group XII, claim 42, drawn to transformed *Salmonella*.

Group XIII, claim 43, drawn to a method of vaccinating.

Group XIV, claim 44, drawn to StpA polypeptide.

Group XV, claim 45, drawn to method of dephosphorylating a protein.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack Unity of Invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for more than one species to be searched, the appropriate additional search fees must be paid. The species are as follows:

The claims are deemed to correspond to the species listed above in the following manner:

species of DNA

INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/18504

DNA(SspA), claims 8-10; SspB, claims 2, 10; SspC, claims 4, 10; SspD, claims 6, 7, 10; SspH, claims 12 and StpA, claims 14.

The following claims are generic:  
For the DNA, claims 1, 10, 16-19.

The species listed above do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: because each DNA encodes a protein which differs physicochemically, antigenically, structurally and functionally.

Form PCT/ISA/210 (extra sheet)(July 1992)\*

# INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/AU 98/00368

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int Cl <sup>6</sup> : C07K 16/20, G01N 33/569, 33/577		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) WPAT, CHEMICAL ABSTRACTS (See Keywords in "Electronic Data Base" box below).		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched JAPIO, USPM, MEDLINE (See Keywords in "Electronic Data Base" box below)		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT, JAPIO, USPM, KEYWORDS: CRYPTOSPORIDI and OOCYST# MEDLINE, CHEMICAL ABSTRACTS, KEYWORDS: CRYPTOSPORIDI? and ANTIBOD? and OOCYST?		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/08204 (MACQUARIE RESEARCH LTD <i>et al.</i> ) 6 March 1997 -see whole document	1-15
X	INFECTION AND IMMUNITY. Vol 60, No 6, (June 1992), pages 2343-2348. Petersen C <i>et al.</i> "Identification and Initial Characterization of Five <i>Cryptosporidium parvum</i> Sporozoite Antigen Genes" -see whole document	1-15
X	PARASITOLOGY (1995), 110, pages 259-268, McDonald V. <i>et al.</i> "Localization of parasite antigens in <i>Cryptosporidium parvum</i> -infected epithelial cells using monoclonal antibodies" -see whole document	1-15
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
* Special categories of cited documents: "A" Document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 18 August 1998		Date of mailing of the international search report 21 AUG 1998
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929		Authorized officer ISOBEL TYSON Telephone No.: (02) 6283 2563

INTERNATIONAL SEARCH REPORT

International Application No.  
PCT/AU 98/00368

C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	INFECTION AND IMMUNITY Vol 59, no 5, (May 1991), pages 1703-1708, Bonnin A <i>et al.</i> "Characterization of Microneme Antigens of <i>Cryptosporidium parvum</i> (Protozoa, Apicomplexa)" -see whole document	1-15
X	PARASITOLOGY RESEARCH (1993), 79:8-14, Bonnin A <i>et al.</i> "A new antigen of <i>Cryptosporidium parvum</i> micronemes possessing epitopes cross-reactive with macrogamete granules" -see whole document	1-15
X	VETERINARY PARASITOLOGY 53 (1994) 159-166, Ortega-Mora L.M. <i>et al</i> "Identification of <i>Cryptosporidium parvum</i> oocyst/sporozoite antigens recognized by infected and hyperimmune lambs" -see whole document	1-15
X	JOURNAL OF EUKARYOTIC MICROBIOLOGY (1995 July - Aug), 42(4), 395-401. BONNIN A <i>et al.</i> "Monoclonal Antibodies Identify a Subset of Dense Granules in <i>Cryptosporidium parvum</i> Zoites and Gamonts". -see whole document	1-15
X	INFECTION AND IMMUNITY (May 1994), 62 (5), pages 1927-1939, Riggs M. W. <i>et al.</i> "Bovine Antibody against <i>Cryptosporidium parvum</i> Elicits a Circumsporozoite Precipitate-Like Reaction and Has Immunotherapeutic Effect against Persistent Cryptosporidiosis in SCID Mice" -see whole document	1-15

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No. <b>PCT/AU98/00368</b>
--

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
WO	97/08204	AU	5146/95	AU	67811/96

END OF ANNEX



P.B.5818 - Patentkant 2  
2280 HV Rijswijk (ZH)  
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Europäisches  
Patentamt

Zweigstelle  
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Recherchen-  
abteilung

European  
Patent Office

Branch at  
The Hague  
Search  
division

Office européen  
des brevets

Département à  
La Haye  
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Perry, Robert Edward  
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Broadgate House  
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GRANDE BRETAGNE

Datum/Date  
03.11.00

Zeichen/Ref./Réf. <b>REP06298EP</b>	Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./Brevet n°. <b>98922500.8-2116-AU9800368</b>
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire <b>Macquarie Research Ltd., et al</b>	

## COMMUNICATION

The European Patent Office herewith transmits as an enclosure the European search report for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

## REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	<p>TILLEY, MICHAEL ET AL: "Multiple oral inoculations with <i>Cryptosporidium parvum</i> as a means of immunization for production of monoclonal antibodies" FEMS MICROBIOL. LETT. (1993), 113(2), 235-40 , XP000941248 * the whole document *</p>	16-19	C07K16/20 G01N33/569 G01N33/577
A	<p>WEE, SUNG-HWAN (1) ET AL: "Diagnosis of bovine cryptosporidiosis by indirect immunofluorescence assay using monoclonal antibody." KOREAN JOURNAL OF PARASITOLOGY, (1995) VOL. 33, NO. 2, PP. 107-115. , XP000942344 * page 108 * * page 109, right-hand column *</p>	1-23	
A	<p>CHO, HYUNG HWAN: "Production of monoclonal antibodies by hybridomas sensitized to sporozoites of <i>Cryptosporidium parvum</i>" SANOP MISAENGMUL HAKHOECHI (1989), 17(5), 494-8 , XP000942320 * page 494, right-hand column * * page 495, left-hand column *</p>	1-23	<p>TECHNICAL FIELDS SEARCHED (Int.Cl.6)</p> <p>C07K</p>
T	<p>FERRARI, B. C. ET AL: "Comparison of <i>Cryptosporidium</i> -specific and <i>Giardia</i>-specific monoclonal antibodies for monitoring water samples" WATER RES. (1999), 33(7), 1611-1617 , XP004160401 * the whole document *</p>	1-23	
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
Place of search		Date of completion of the search	Examiner
MUNICH		20 October 2000	Mennessier, T
CATEGORY OF CITED DOCUMENTS			
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			



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Patentamt

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Recherche-  
abteilung

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Patent Office

Branch at  
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Search  
division

Office européen  
des brevets

Département à  
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GRANDE BRETAGNE

Datum/Date  
03.11.00

ZeichenRef./Réf. REP06298EP	Anmeldung Nr./Application No./Demande n°/Patent Nr./Patent No./Brevet n°. 98922500.8-2116-AU9800368
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire Macquarie Research Ltd., et al	

## COMMUNICATION

The European Patent Office herewith transmits as an enclosure the European search report for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

## REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.





DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl6)
X	<p>TILLEY, MICHAEL ET AL: "Multiple oral inoculations with <i>Cryptosporidium parvum</i> as a means of immunization for production of monoclonal antibodies" FEMS MICROBIOL. LETT. (1993), 113(2), 235-40, XP000941248 * the whole document *</p> <p>---</p>	16-19	C07K16/20 G01N33/569 G01N33/577
A	<p>WEE, SUNG-HWAN (1) ET AL: "Diagnosis of bovine cryptosporidiosis by indirect immunofluorescence assay using monoclonal antibody." KOREAN JOURNAL OF PARASITOLOGY, (1995) VOL. 33, NO. 2, PP. 107-115., XP000942344 * page 108 * * page 109, right-hand column *</p> <p>---</p>	1-23	
A	<p>CHO, HYUNG HWAN: "Production of monoclonal antibodies by hybridomas sensitized to sporozoites of <i>Cryptosporidium parvum</i>" SANOP MISAENGMUL HAKHOECHI (1989), 17(5), 494-8, XP000942320 * page 494, right-hand column * * page 495, left-hand column *</p> <p>---</p>	1-23	TECHNICAL FIELDS SEARCHED (Int.Cl6) C07K
T	<p>FERRARI, B. C. ET AL: "Comparison of <i>Cryptosporidium</i> -specific and <i>Giardia</i>-specific monoclonal antibodies for monitoring water samples" WATER RES. (1999), 33(7), 1611-1617 , XP004160401 * the whole document *</p> <p>---</p>	1-23	
The supplementary search report has been based on the last set of claims valid and available at the start of the search.			
1	Place of search MUNICH	Date of completion of the search 20 October 2000	Examiner Mennessier, T
CATEGORY OF CITED DOCUMENTS			
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons &amp; : member of the same patent family, corresponding document</p>			
EPO FORM 1503.03.82 (P04C04)			

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 80456	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No.  PCT/AU 98/00368	International filing date (day/month/year)  19 May 1998	Priority Date (day/month/year)  19 May 1997
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>6</sup> C07K 16/20, G01N 33/569, 33/577		
Applicant Macquarie Research Ltd, et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
 

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheet(s).
3. This report contains indications relating to the following items:
 

I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 3 December 1998	Date of completion of the report 17 March 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer  ISOBEL TYSON  Telephone No. (02) 6283 2563

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed.

the description, pages 1-29, as originally filed,  
pages , filed with the demand,  
pages , filed with the letter of .

the claims, pages 31, as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 30, filed with the letter of 24 February 1999.

the drawings, pages 1/4-4/4, as originally filed,  
pages , filed with the demand,  
pages , filed with the letter of .

the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , filed with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

the description, pages

the claims, Nos.

the drawings, sheets/fig

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-23 Claims	YES NO
Inventive step (IS)	Claims 1-23 Claims	YES NO
Industrial applicability (IA)	Claims 1-23 Claims	YES NO

**2. Citations and explanations (Rule 70.7)**

**NOVELTY (N) and INVENTIVE STEP (IS): Claims 1-23**

The present invention of claims 1-23 is considered novel and inventive.

The following documents are considered relevant art:

• **Parasitology, 110 (1995) pp 259-98**

The methods of antibody production disclosed in this document are different to those of the present claimed invention. Additionally, the antibodies produced were not IgG1 subclass, and the monoclonal antibody to the oocyst wall was an IgM, not IgG1.

Thus, this document does not disclose nor teach toward the present claimed invention.

• **Infection and Immunity, 59(5), May 1991, pp 1703-08**

The IgG mAbs produced by the methods disclosed in this document reacted with the sporozoites rather than the oocyst wall which was a requirement of the present claimed invention.

Further, immunisation was with the excysted oocysts rather than the oocyst antigen preparation of the present claimed invention.

Thus, this document neither discloses nor teaches toward the present claimed invention.

• **Vet. Parasit., 53, (1994), pp 159-66**

This document does not disclose nor teach toward producing the isolated IgG1 subclass antigens which react to the surface of Cryptosporidium oocysts.

Further, it is directed to immunising with whole oocysts which produces IgM antibodies only.

Thus, the present claimed invention is novel and inventive in light of the document.

• **Infection and Immunity, 62(5), May 1994, pp 1927-39**

Immunisation was also with whole oocysts. There is no disclosure or any teaching toward producing isolated IgG1 antibodies which react to the surface of the oocysts.

The present claimed invention is therefore novel and inventive in light of this document.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

On page 2, there are several references to prior art that are identified only by author name and year. As there is no bibliography or reference section, it is impossible to locate these documents.

ATLNT COOPERATION TREATY  
PCT  
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 06 APR 1999

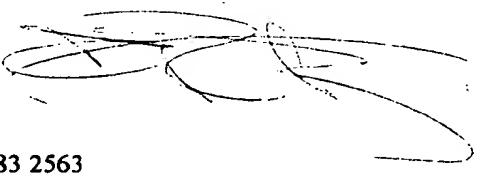
WIPO

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 80456	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International application No. <b>PCT/AU 98/00368</b>	International filing date (day/month/year) 19 May 1998	Priority Date (day/month/year) 19 May 1997	
International Patent Classification (IPC) or national classification and IPC <b>Int. Cl. 6 C07K 16/20, G01N 33/569, 33/577</b>			
<b>Applicant</b> Macquarie Research Ltd, et al.			

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.		
2.	This REPORT consists of a total of <b>5</b> sheets, including this cover sheet.  <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <b>1</b> sheet(s).		
4 + 1			
3.	This report contains indications relating to the following items:		
I	<input checked="" type="checkbox"/> Basis of the report		
II	<input type="checkbox"/> Priority		
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability		
IV	<input type="checkbox"/> Lack of unity of invention		
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
VI	<input type="checkbox"/> Certain documents cited		
VII	<input type="checkbox"/> Certain defects in the international application		
VIII	<input checked="" type="checkbox"/> Certain observations on the international application		

Date of submission of the demand <b>3 December 1998</b>	Date of completion of the report <b>17 March 1999</b>
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer  <b>ISOBEL TYSON</b> Telephone No. (02) 6283 2563

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed.

the description, pages 1-29, as originally filed,  
pages , filed with the demand,  
pages , filed with the letter of .

the claims, pages 31, as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages 30, filed with the letter of 24 February 1999.

the drawings, pages 1/4-4/4, as originally filed,  
pages , filed with the demand,  
pages , filed with the letter of .

the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , filed with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

the description, pages

the claims, Nos.

the drawings, sheets/fig

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims 1-23	YES
	Claims	NO
Inventive step (IS)	Claims 1-23	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-23	YES
	Claims	NO

**2. Citations and explanations (Rule 70.7)**

**NOVELTY (N) and INVENTIVE STEP (IS): Claims 1-23**

The present invention of claims 1-23 is considered novel and inventive.

The following documents are considered relevant art:

• Parasitology, 110 (1995) pp 259-98

The methods of antibody production disclosed in this document are different to those of the present claimed invention. Additionally, the antibodies produced were not IgG1 subclass, and the monoclonal antibody to the oocyst wall was an IgM, not IgG1.

Thus, this document does not disclose nor teach toward the present claimed invention.

• Infection and Immunity, 59(5), May 1991, pp 1703-08

The IgG mAbs produced by the methods disclosed in this document reacted with the sporozoites rather than the oocyst wall which was a requirement of the present claimed invention.

Further, immunisation was with the excysted oocysts rather than the oocyst antigen preparation of the present claimed invention.

Thus, this document neither discloses nor teaches toward the present claimed invention.

• Vet. Parasit., 53, (1994), pp 159-66

This document does not disclose nor teach toward producing the isolated IgG1 subclass antigens which react to the surface of *Cryptosporidium* oocysts.

Further, it is directed to immunising with whole oocysts which produces IgM antibodies only.

Thus, the present claimed invention is novel and inventive in light of the document.

• Infection and Immunity, 62(5), May 1994, pp 1927-39

Immunisation was also with whole oocysts. There is no disclosure or any teaching toward producing isolated IgG1 antibodies which react to the surface of the oocysts.

The present claimed invention is therefore novel and inventive in light of this document.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

On page 2, there are several references to prior art that are identified only by author name and year. As there is no bibliography or reference section, it is impossible to locate these documents.

ATENT COOPERATION TREATY  
**PCT**  
 INTERNATIONAL PRELIMINARY EXAMINATION REPORT

REC'D 06 APR 1999

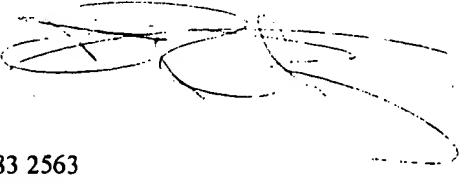
WIPO

PCT

(PCT Article 36 and Rule 70)

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Date of submission of the demand 3 December 1998	Date of completion of the report 17 March 1999
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. (02) 6285 3929	Authorized Officer   ISOBEL TYSON Telephone No. (02) 6283 2563

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**1. Statement**

Novelty (N)	Claims 1-23 Claims	YES NO
Inventive step (IS)	Claims 1-23 Claims	YES NO
Industrial applicability (IA)	Claims 1-23 Claims	YES NO

**2. Citations and explanations (Rule 70.7)**

**NOVELTY (N) and INVENTIVE STEP (IS): Claims 1-23**

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Further, it is directed to immunising with whole oocysts which produces IgM antibodies only.

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Immunisation was also with whole oocysts. There is no disclosure or any teaching toward producing isolated IgG1 antibodies which react to the surface of the oocysts.

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